



יולי 2019

**Tecentriq® 1200mg/20ml
atezolizumab
Concentrate for solution for infusion**

רופא/ה יקר/ה, רוקח/ת יקר/ה,
חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על מספר עדכונים שבוצעו בעלון לרופא
של התכשיר טיסנטריק.

בהודעה זו מצוינים רק עדכונים מהותיים ועדכונים אשר מהווים חמרה.

ההתוויות הרשומות לתכשיר בישראל:

Locally Advanced or Metastatic Urothelial Carcinoma

TECENTRIQ (atezolizumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumours have a PD-L1 expression $\geq 5\%$.

TECENTRIQ is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following any platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant chemotherapy.

Metastatic Non-Small Cell Lung Cancer

TECENTRIQ is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) who are naïve to anti-PD-L1 or anti-PD-1 therapies and have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on approved therapy for these aberrations prior to receiving TECENTRIQ.

למידע נוסף יש לעיין בעלון לרופא כפי שנשלח למשרד הבריאות.
העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס ע"י
פנייה לבעל הרישום: רוש פרמצבטיקה (ישראל) בע"מ, ת.ד. 6391, הוד השרון 4524079
טלפון 09-9737777. כתובתנו באינטרנט: www.roche.co.il.

ב ב ר כ ה,

לילי אדר
רוקחת ממונה

בתאור צפרי-חגג
מחלקת רישום

עדכונים מהותיים בעלון לרופא

בפתיחת העלון התווספה פיסקה המיידעת על קיומה של תוכנית למזעור סיכונים:

Patient safety information card and brochure

The marketing of TECENTRIQ is subject to a risk management plan (RMP) including patient safety information materials (patient information card and patient brochure). These materials emphasizes important safety information that the patient should be aware of before and during treatment. Please explain to the patient the need to review these materials before starting treatment.

Prescriber guide

This product is marketed with prescriber guide providing important safety information. Please ensure you are familiar with this material as it contains important safety information.

בסעיף **1 Indications and usage** עודכן המידע הבא:

1.1 Locally Advanced or Metastatic Urothelial Carcinoma

TECENTRIQ (atezolizumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumours have a PD-L1 expression $\geq 5\%$.

בסעיף **2 Dosage and administration** נוסף המידע הבא:

2.1 Patient Selection for Treatment of Urothelial Carcinoma

Select cisplatin-ineligible patients with previously untreated locally advanced or metastatic urothelial carcinoma for treatment with TECENTRIQ based on the PD-L1 expression on tumor-infiltrating immune cells [see Clinical Studies (14.1)].

ועודכן המידע הבא:

2.4 Preparation and Administration

Storage of Infusion Solution

This product does not contain a preservative.

Administer immediately once prepared. If diluted TECENTRIQ infusion solution is not used immediately, store solution either:

- At ambient temperature ($\leq 30^{\circ}\text{C}$ to 25°C) for no more than 8 hours from the time of preparation. This includes room temperature storage of the infusion in the infusion bag and time for administration of the infusion, or
- Under refrigeration at 2°C to 8°C for no more than 24 hours from time of preparation.
- From a microbiological point of view, the prepared solution for infusion should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C or 8 hours at ambient temperature ($\leq 25^{\circ}\text{C}$).